

REMARKS

In the October 4, 2006 Office Action, the Examiner has required restriction under 35 U.S.C. §121 of the claims to one of the following allegedly distinct inventions:

- I. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:1 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- II. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:2 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- III. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:3 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- IV. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:4 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- V. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:5 or its complement, vectors comprising said nucleic acid, host cells transformed with

said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.

- VI. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:6 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- VII. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:7 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- VIII. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:8 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- IX. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:9 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- X. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:10 or its complement, vectors comprising said nucleic acid, host cells transformed with

said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.

- XI. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:11 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- XII. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:12 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- XIII. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:13 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.
- XIV. Claims 1-11, drawn to an isolated nucleic acid encoding SEQ ID NO:14 or its complement, vectors comprising said nucleic acid, host cells transformed with said vectors and recombinant production using said host cells, classified in class 435, subclass 69.1.

In response to the Examiner's restriction requirement, Applicant has canceled claims 1-11 without prejudice to Applicant's rights to pursue these claims in another application,

and added new claims 12-54. Support for the new composition claims may be found in the specification, for example, on pages 3 and 39, Example 17, specifically in Table 18. Support for the new method claims may be found on pages 13-14 and Examples 3-18 (on pages 16-42). No new matter has been added. Accordingly, claims 12-54 are now pending in the present application.

The Examiner alleges on page 5 that the inventions “have acquired a separate status in the art as shown by their different classification.” However, the classifications (and subclassifications) are the exact same for each group, i.e., class 435, subclass 69.1. Furthermore, the polypeptides encoded by the nucleotide sequences of the different sequence listings are related as immunogenic *Leishmania* polypeptide compounds having immunotherapeutic properties. Therefore, even if Applicants did not cancel claims 1-11, there would be no undue search burden for the Examiner with regard to these claims.

New claims 11-54 of the present invention are directed to compositions and methods for treatment of symptoms of psoriasis comprising at least one immunogenic polypeptide and fragments thereof isolated from the particulate fraction of at least one protozoan of genus *leishmania*, wherein the at least one immunogenic polypeptide inhibits inflammation associated with psoriasis, and wherein the apparent molecular weights of the immunogenic polypeptides in the composition after total reduction and alkylation are 82kD, 80kD and 73kD.

The specification expressly teaches and discloses that the effective agent of the present invention is a compound comprising an immunotherapeutic agent, the

immunotherapeutic agent comprising a particulate antigen, and the antigen comprising immunogenic polypeptides of 73, 80 and 82 kDa molecular weight that are to be combined and used together as an immunogen to vaccinate humans. It further teaches and discloses that the immunotherapeutic agent comprises an insoluble particulate antigen, and that the insoluble particulate antigen in turn comprises *Leishmania* polypeptides having apparent molecular weights after total reduction and alkylation of about 73 kDa, about 80 kDa and about 82 kDa. Page 16, lines 20-23, for example, discloses that “the immunogen preparations of the second-generation immunotherapeutic agent, which contains protein fractions 3 and 4 obtained after DEAE-chromatography and total reduction and alkylation had three bands with molecular weights of 73, 80 and 82 kDa.” Example 17 and Table 18 teach that the fractions used as immunogens that induce clinical remission of psoriatic lesions each contain 73 kD, 80 kD and 82 kDa polypeptides.

The present invention now claims a compound comprising an immunotherapeutic agent comprising an antigen comprising these immunogenic *Leishmania* polypeptides, and methods for treatment comprising using the claimed compound. The literature search required for these new claims would impose no additional burden on the Examiner.

Since Applicant has canceled claims 1-11, and new claims 12-54 render the Examiner's restriction requirement moot, Applicant respectfully requests that the Examiner withdraw the requirement.

Conclusion

Applicant earnestly solicits early and favorable action by the Examiner. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is respectfully urged to telephone the undersigned at (973) 597-6170. The undersigned also may be contacted via e-mail at blubit@lowenstein.com.


AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. 501,358.

Respectfully submitted,

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